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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,225	01/08/2001	Miri Blank	BLANK 3	7300
1444	7590	02/13/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			LUKTON, DAVID	
624 NINTH STREET, NW			ART UNIT	
SUITE 300			PAPER NUMBER	
WASHINGTON, DC 20001-5303			1653	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,225

Applicant(s)

BLANK ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-12 and 22-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11, 12, 22 and 23 is/are rejected.
7) ☒ Claim(s) 8-10 and 24 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the response filed 11/25/03, claim 25 has been added (no claim has been amended). Claims 8-12, 22-25 are now pending.

Claim 25 is withdrawn from consideration, since it does not encompass the elected specie. In the elected specie, the peptide present was that of SEQ ID NO: 3, and no indication was given that even one of the amino acids present might be replaced with a non-natural amino acid; certainly none of the amino acids of claim 25 was mentioned in the election.

Applicants' arguments filed 6/12/03 have been considered and found not persuasive. Claims 11, 12, 22, 23 remain rejected; claims 8-10 and 24 are objected to because of their dependence on rejected claims.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 12, 22-23 are rejected under 35 U.S.C. §102(e) as being anticipated by Buchardt (USP 6,414,112).

As indicated previously, Buchardt discloses (e.g., figure 2) peptide nucleic acids. Buchardt does not disclose any of SEQ ID NOS: 1, 4, or 7.

This rejection focuses on the following phrase in claim 22:

“a modified derivative... in which ... the amino acid residues have been replaced by ... a non-natural amino acid residue”.

Thus, if each of the amino acids in SEQ ID NO: 1 or 4 or 7 is deleted and replaced by one of the amino acids disclosed in Buchardt, the requirements of the claims would be met.

The response filed 11/25/03 argues that Buchardt does not disclose non-natural amino acids attached to a backbone. First, it is very clear that Buchardt discloses compounds that contain non-natural amino acids; no reason has been given as to why one would not conclude this. The principal basis of the traversal appears to be that the reference does not teach a “backbone”. However, the term “backbone”, without further qualification, is subject to broad interpretation. Consider, for example, the following peptide:

Asp-Asp-Asp-Asp-Phe-Phe-Phe-Phe-Phe-Gly-Gly-Gly-Gly

This peptide consists of three segments, i.e., (Asp)₄, (Phe)₅ and (Gly)₄. Any one of these three can qualify as a “backbone”; any one of these would qualify as a “chain”. If the (Phe)₅ segment is the “backbone”, and the (Asp)₄ and (Gly)₄ are “chains”, then the peptide (Asp)₄-(Phe)₅-(Gly)₄ would qualify as a “multichain peptide oligomer

conjugate”. Similar to the foregoing, Buchardt discloses compounds which qualify as both peptides and oligomers, wherein most of the amino acids are “non-natural”. Accordingly, a middle segment of the oligomer would qualify as a “backbone”, and the remaining amino acid units would qualify as the peptide or oligomer. The claims do not require that the “conjugate” be branched. The claims permit the “conjugate” to be an unbranched, linear oligomer containing unnatural amino acids. This limitation is met by the reference; the rejection is maintained.

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Claims 11, 12, 22-23 are rejected under 35 U.S.C. §102(b) as being anticipated by Nametz (USP 4,141,880).

As indicated previously, Nametz discloses (col 1, line 31) poly-aminocaproic acid.

As with the §102 rejection over Buchardt ('112), this rejection focuses on the following phrase in claim 22:

“a modified derivative... in which ... the amino acid residues have been replaced by ... a non-natural amino acid residue”.

If one were to replace each of the amino acids in SEQ ID NO: 1 or 4 or 7 with aminocaproic acid, and then covalently bond each of those “modified derivatives” with an oligomer of aminocaproic acid, the result would be the polymer that is disclosed in Nametz.

The response argues that, while it is true that Nametz discloses a polymer of aminocaproic

acid, this does not amount to a series of “non-natural amino acids attached to a backbone”. First, aminocaproic acid is a “non-natural amino acid”, and this point has not been questioned. As for the issue of the “backbone”, let the polyaminocaproic acid be represented as follows (“ACA” = aminocaproic acid):



wherein “n”, “p” and “r” represent integers. As such, the segment $(ACA)_p$ is the “backbone”, and the segments $(ACA)_n$ and $(ACA)_r$ are oligomer “chains”. Suppose that the sum of n, p and r is 1000. Suppose further that each of the amino acids in SEQ ID NO:1 has been replaced with the “non-natural amino acid” aminocaproic acid, giving rise to $(ACA)_6$ and that each of the amino acids in SEQ ID NO:4 has also been replaced with aminocaproic acid, giving rise to $(ACA)_{11}$. The “backbone” of the polymer is then $(ACA)_p$ wherein “p” is the number 983. As indicated above (the §102(e) over Buchardt), the claims do not require that the “conjugate” be branched; the claims permit the “conjugate” to be an unbranched, linear oligomer containing unnatural amino acids. This limitation is met by the reference; the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE

EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 4/11/04

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800